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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,143	11/12/2001	Carol W. Readhead	18810-81609	6154

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,143

Applicant(s)

READHEAD ET AL.

Examiner

Joseph T. Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 135-137 and 143-145 is/are pending in the application.
- 4a) Of the above claim(s) 138-142 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 135-137 and 143-145 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This application filed November 12, 2001, is a divisional of application 09/191,920, filed November 13, 1998, now US Patent 6,316,692, which claims benefit to provisional application 60/065,825, filed November 14, 1997.

Applicants' preliminary amendment filed August 22, 2003 has been received and entered. The specification has been amended.

Claims 135-145 are pending.

Election/Restriction

Applicant's election of Group I, and the election of the species of a retroviral vectors is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 136 and 137 specifically recite the elected transfecting agent of a retroviral vector and claims 135, 143, 144 and 145 are generic to the elected invention. Claims 138-142 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Claims 135-137 and 143-145 are currently under examination to the extent they encompass the elected invention drawn to a kit comprising: (1) a retroviral vector as a transfecting agent, (2) a polynucleotide comprising a gene in operable linkage with a promoter, and optionally (3) a polynucleotide encoding a selectable genetic marker.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

In Applicants' amendment filed November 12, 2001, the first line of the specification was amended to indicate the claim for priority. See Applicants' amendment filed November 12, 2001, page 6. However, the amendment does not provide all the relevant serial numbers of the applications of which the instant application claims benefit.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

It is noted that this application appears to claim subject matter disclosed in prior Applications, however the application serial numbers have not been provided. A reference to the prior application must be inserted as the first sentence of the specification of this application or

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in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the

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claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Claim Objections

Claims 135-137 and 143-145 are objected to because of the following informalities: it is noted that upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. However, no generic claim is found allowable and the claims broadly encompass non-elected inventions. The claims should be amended to reflect the elected invention.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 135-137, 143-145 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 135 is vague and unclear in the relationship of the specific limitations set forth in the claim. Specifically, Applicants have elected a kit comprising: (1) a retroviral vector as a transfecting agent, (2) a polynucleotide comprising a gene in operable

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linkage with a promoter, and optionally (3) a polynucleotide encoding a selectable genetic marker, and it is unclear if (2) and (3) are comprised in the retroviral vector or if they represent separate and different components in addition to the retroviral vector. It is unclear if the claim encompasses three separate components and if not, how are the three components physically related one to the other in the kit. Dependent claims fail to further define the physical relationship, only setting forth further details of the types of components contemplated.

Claims 143-145 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claims set forth limitations for the genetic selection marker, however in claim 135, from which these depend, this marker is optional. It is unclear if these claims require the presence of a genetic selection marker, or only if it is “optionally” present, that it has the limitations set forth in the claims. More clearly setting forth the requirement for the genetic selection marker in claims 143-145 would obviate the basis of the rejection.

Claims 143 and 144 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 143 sets forth that the expression of the marker is driven by a “spermatogonia-specific promoter”, and claim 144 sets forth the names of several specific promoters, however none of these are expressed only in spermatogonia cells. Moreover, the specific sequences for these gene promoters encompassed by the claims are not taught in the specification, and though some may be taught or known in the art, the claims encompass the gene promoters from any species of organism. Even if it may be that one gene

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promoter from one species would provide specific expression of a marker in the spermatogonia cell of that species, the inability of the same promoter to provide the same expression in a different species makes the claim indefinite because the function defining it as a spermatogonia specific promoter would depend on the intended use of the promoter/kit. The metes and bounds of the product as claimed are indefinite because they can only be defined by the intended use of the product which is subject to change and carries no patentable weight in a product claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 135-137 and 145 are rejected under 35 U.S.C. 102(b) as being anticipated by Bosselman *et al.* (US Patent 5,162,215).

Please note that this reference is not relied upon as a showing of the use of the product for the transfection spermatogonia cells. This is because the claim recitation “for the transfection of a male non-human vertebrate’s germ cells” has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

The claims encompass a composition comprising: (1) a retroviral vector as a transfecting agent, (2) a polynucleotide comprising a gene in operable linkage with a promoter, and optionally (3) a polynucleotide encoding a selectable genetic marker. Bosselman *et al.* teach a recombinant retroviral vector containing a gene of interest. Bosselman *et al.* teach that any gene of interest can be provided such as hormones (see claim 5) and includes the teaching for use of a selectable marker genes such as neomycin (see claim 4). Bosselman *et al.* teaches that the retroviral vectors can be used to transfect mouse egg cells, male pronuclei (column 1, starting on line 46 and column 3, starting on line 21). Bosselman *et al.* provide a retroviral vector that anticipates the limitations set forth in the claims and provides the same intended use for the vector for transfecting germ cells.

With respect to the written instructions, the CAFC in *In re Gulack* 217 USPQ 401 1983 stated that printed matter that is not functionally related to the substrate does not distinguish the invention from the prior art in terms of patentability; although printed matter must be considered, in that situation it may not be entitled to patentable weight (page 401). The court further stated that the critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate (page 404 "B"). Evidence is not of record that the notice from a governmental agency would affect the function of the polynucleotide claimed. The CAFC in *In Re Woodruff* 16 USPQ2d 1934 indicated that new uses for old compounds does not necessarily provide patentability to the old compound. The court, in replying to arguments of *In re Shetty* 195 USPQ 753 and *In Re Marshall* 198 USPQ 344, indicates that for new uses for old or obvious compounds to be patentable the claimed uses must be "completely new". Applicant's retroviral vector containing a polynucleotide encoding a gene product and optionally a marker is

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not disclosed as having a "completely new" use as it was well known in the art at the time of filing to use retroviral vectors to transfect cells and to provide the expression of heterologous transgenes.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 6,426,042 B1 (Asada *et al.*) teaches a kit comprising a recombinant retroviral vector for the expression of a transgene in a cell of interest. Based on the priority information, this is a 102(e) type reference, and is provided to demonstrate that at the time of filing retroviral vectors were well known and used in methods to transfect a cell of interest.

No claim is allowed. Claims 143 and 144 are free of the art of record however they are subject to other rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

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